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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/777,283 | 02/11/2004 | John F. Shanley | P067 | 5462 |

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EXAMINER

SILVERMAN, ERIC E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/777,283 | Applicant(s) SHANLEY ET AL. | |
| | Examiner Eric E. Silverman, PhD | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-51 is/are pending in the application.
 4a) Of the above claim(s) 38-47 and 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21-37 and 41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9-30-04, 2-11-04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt of Applicants' response to Election/Restriction requirement, filed 4/19/2006 is acknowledged. Applicant elected Group I, claims 21 – 37 and 48, directed to a method of making an implant. As such, claims 38 – 44, and 49 – 51 are withdrawn from consideration as being drawn to a non-elected invention, and claims 21 – 37 and 48 are considered on the merits in this action.

It is noted that applicants did not allege any error in Examiners restriction requirement, and as such, the election is being treated as **without traverse**.

Claim Objections

Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 recites coating the body of the medical device with the first homogeneous solution, and depends from claim 21. Claim 21 recites applying the first homogeneous solution to the expandable medical device, and then solidifying it, thus forming a coating. As such, claim 30 has exactly the same scope as claim 21.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the specification of a barrier material that forms a barrier to the passage of the therapeutic agent in the first homogeneous solution to one side of the body of the device. The barrier layer is discussed in paragraph 0064 of the specification, where it is described to have the opposite effect, that is, to allow diffusion of the agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 29, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation "a recess in the body of the expandable medical device" in claim 21. There is insufficient antecedent basis for this limitation in the claim. Claim 21 recites neither an "expandable medical device" nor a "recess in the body" thereof.

Claim 29 recites the limitation "an opening passing through the implantable medical device body" in claim 21. There is insufficient antecedent basis for this limitation in the claim.

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Claim 34 is confusing. It is unclear what constitutes the "barrier layer". The specification only adds to this confusion, since the purpose of this layer as described in the specification (paragraph 0064) is to encourage diffusion of the therapeutic agent, whereas the claim recites that this layer should prevent such diffusion. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 – 37 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,624,411 to Tuch, of record.

Tuch teaches a method of making a stent by contacting the body thereof with a solution of polymer and therapeutic agent (abstract, paragraph bridging col.'s 2 and 3, col. 4 line 32 – col. 5 line 14) followed by evaporating the solvent, and subsequently applying an "overlayer" to this coating by dissolving either a polymer or a polymer and a therapeutic agent in a solvent, contacting this solution with the stent onto which the first layer has been applied, and evaporating the solvent (col. 6, lines 32 – 63). The application of the overlayer is disclosed to liquefy part of the first layer by dissolution, and result in a concentration gradient in the drug/polymer coating. Although the concentration of the therapeutic agent in the overlayer-forming solution is not mentioned, it is clear that it must be different from that in the first solution, since the

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express purpose of the application of the overlayer is to form a concentration gradient, and since such a gradient is disclosed to be formed. No concentration gradient would be formed if the therapeutic was of the same concentration in both layers. The drugs, solvents and polymers used are disclosed in Table 1, and are commensurate in scope with instant claims. Furthermore, although the text on col. 4 lines 31 – 46 states that the drug may be either dispersed or dissolved in the solvent, a dissolution is exemplified (examples 3 and 4), and so a homogeneous solution is clearly a preferred embodiment. Applying multiple thin coats of the drug-polymer solution is also disclosed (col. 4, lines 32 – col. 5 line 14), which reads on the “barrier layer” as recited in claim 34, since no therapeutic agent is disclosed to pass to any side of the implant to which it is not applied.

Conclusion

No claims are allowed. No claims are free of the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615


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